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DISSOLUTION PERFORMANCE VERIFICATION STANDARD - PREDNISONE

(10 mg nominal prednisone content per tablet)

USP Catalog No.:	1222818
USP Lot No.:	R271J0
Bulk Lot No:	B250038

Valid Use Date	30-SEP-2027
Storage/Handling	As per the label.
Uses	General Chapter <711> Dissolution, Performance Verification Test (PVT), Apparatus 1 and Apparatus 2

Dissolution <711>

Medium:	499 g of degassed purified water maintained at 37° ± 0.5°
Medium degassing:	Recommended degassing procedure: Heat a suitable amount of water, while stirring gently to about 41-45°. Filter under vacuum through a 0.45-µm-porosity filter into a suitable filtering flask equipped with a stirring device. Seal the flask and continue to apply vacuum while stirring for an additional five minutes. Measured vacuum should be less than 100 mbar. **Note**: Other validated degassing methods that reduce the total dissolved gas in the media can also be used.
Apparatus:	Apparatus 1 (Basket) or Apparatus 2 (Paddle) at 50 RPM Note: If equipment is dedicated for use with only one apparatus (basket or paddle), then performance verification is only required for that apparatus.
Time:	30 minutes
Standard solution:	A known concentration of USP Prednisone RS in Medium. **Note**: An amount of methanol or ethanol not to exceed 5% of the total volume of the standard solution may be used to bring the prednisone reference standard into solution.
Sample solution:	Laboratory can choose either Single-Stage Test or Optional Two-Stage Test scheme to obtain Sample Solutions. A filtered portion of the solution under test, suitably diluted, if necessary, with Medium to obtain a concentration similar to that of the Standard solution. **Note 1**: The filtering method must not cause adsorptive loss of drug (using 0.45-µm PVDF material or equivalent). **Note 2**: Bias introduced by automated methods is to be avoided.
Analysis:	UV at 242 nm

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Dissolution <711>

Procedure: Determine the quantity of prednisone, $C_{21}H_{26}O_5$, dissolved at 30 minutes in each vessel expressed as percent of the labeled amount.

Single-Stage Test Instructions and Acceptance Criteria

1. For each position in the assembly, test one USP Dissolution Performance Verification Standard – Prednisone (DPVS – Prednisone) RS tablet, and record the percent dissolved at the sampling time point specified. Transform the percent dissolved results to the natural log scale, determine the mean and variance. For assemblies with 12 or 14 dissolution vessels, no further testing is required.
2. For assemblies with fewer than 12 positions, repeat Step 1 with an additional set of tablets. Transform the percent dissolved results to the natural log scale, determine the mean and variance.
3. Calculate the average of the two means and of the two variances obtained in Steps 1 and 2.

   Use the results from Step 1 alone for assemblies that have 12 or 14 positions.
4. Convert the results of Step 3 to a geometric mean (GM) and percent coefficient of variation (%CV). See Calculation Example for details.
5. Compare the results of Step 4 to the Single-Stage acceptance criteria in Table 1. The GM must not fall outside the limits, and the %CV must not be greater than the limit. If both meet the criteria, the assembly has passed the PVT.

Table 1. Performance Verification Test Acceptance Criteria for Single-Stage Test

Apparatus	No. of vessels per run	Geometric Mean, % Prednisone Dissolved	%CV
1 (Basket)	6	78-93	4.3
	7	79-93	4.2
	8	79-93	4.1
	12	78-93	4.2
	14	79-93	4.1
2 (Paddle)	6	45-56	5.9
	7	45-56	5.8
	8	45-55	5.7
	12	45-56	5.9
	14	45-55	5.8

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Optional Two-Stage Test Instructions and Acceptance Criteria

A laboratory may choose to implement the PVT as a Two-Stage test in case of assemblies with less than 12 positions. The Two-Stage test is a statistically valid means of allowing the possibility of stopping the test at the first stage using more stringent acceptance criteria. The following are step-by-step instructions for the two-stage test.

1. For each position in the assembly, test one USP DPVS – Prednisone RS tablet, and record the percent dissolved at the sampling time point specified. Transform the percent dissolved results to the natural log scale, determine the mean and variance.
2. Convert the results of Step 1 to a GM and %CV and compare to the 1st Stage of Two Stages acceptance ranges in Table 2. The GM must not fall outside the limits, and the %CV must not be greater than the limit. For calculation of the GM and %CV, see Calculation Example for details.
3. If results of Step 2 satisfy both acceptance criteria, the assembly has passed the PVT. Otherwise continue to Step 4. Prior to proceeding to Step 4, see Futility Factor section.
4. Repeat Step 1 with an additional set of tablets. Transform the percent dissolved results to the natural log scale determine the mean and variance for the data obtained at this step.
5. Average the two means and two variances obtained in Steps 1 and 4.
6. Convert the results of Step 5 to a geometric mean (GM) and percent coefficient of variation (%CV). For calculation of the GM and %CV, see Calculation Example for details.
7. Compare the results of Step 6 to the 2nd Stage of Two Stages acceptance ranges in Table 2. The GM must not fall outside the limits, and the %CV must not be greater than the limit. If both meet the acceptance criteria, the assembly has passed the PVT.

Table 2. Performance Verification Test Acceptance Criteria for Two-Stage Test

Apparatus	No. of vessels per run	First Stage of Two-Stage Test		Second Stage of Two-Stage Test	
		Geometric Mean, % Prednisone Dissolved	%CV	Geometric Mean, % Prednisone Dissolved	%CV
1 (Basket)	6	81-90	3.2	78-93	4.3
	7	81-90	3.2	79-93	4.2
	8	81-90	3.2	79-93	4.1
2 (Paddle)	6	47-53	4.5	45-56	5.9
	7	47-53	4.5	45-56	5.8
	8	47-53	4.5	45-55	5.7

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Futility Factor

If optional Stage-Two test is chosen, there are circumstances when the %CV after the First Stage of Two-Stage test equals or exceeds the value in the Futility Factor table (without rounding). In such cases it is impossible to meet the %CV criterion after the Second Stage of the Two-Stage test. The lab can stop after the First Stage run. However, after any adjustments to equipment, test procedure, and so on, the PVT must be restarted with a new first run (Step 1 of the two-stage test instructions).

Futility Factor, %CV at or above value given, second stage testing will not produce passing result

Apparatus	Number of Vessels		
	6	7	8
1	6.1	5.9	5.8
2	8.4	8.2	8.1

Refer to this website for the USP Calculation Tool: https://apps.usp.org/app/USPNF/pvtCalculationTool/

Calculation Example (expressed as Microsoft Excel® worksheet functions)**:**

Run 1: $x_1, x_2, \ldots, x_n$ in natural log scale: Ln x_1, Ln x_2, …, Ln x_n

Run 2: $x_{n+1}, x_{n+2}, \ldots, x_{2n}$ in natural log scale: Ln x_{n+1}, Ln x_{n+2}, …, Ln x_{2n}

1st Stage of Two-Stage for n=6, 7, 8 and Single-Stage for n=12, 14:

GM1 = exp(average (Ln x_1:Ln x_n))

%CV1 = 100*sqrt(exp(var(Ln x_1:Ln x_n)) -1)

Single-Stage or 2nd Stage of Two-Stage for n= 6, 7, 8:

GM = exp(average((average (Ln x_1:Ln x_n)), (average (Ln x_{n+1}:Ln x_{2n})))) = exp(average (Ln x_1:Ln x_{2n}))

%CV= 100*sqrt(exp(average((var(Ln x_1:*Ln* x_n)),(var(Ln x_{n+1}:Ln x_{2n})))) -1)

exp: exponential (e^x) var: variance sqrt: square root *: multiply 100: conversion factor to percentage

For more information and guidelines about how to complete the performance verification test refer to the following website: https://www.usp.org/small-molecules/pvt

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Label



Timothy Bowen

Quality Assurance

Certificate Version History

Version Number	Date	Reasons for Change
00	27-OCT-2026	First issue

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